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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/595,947	06/16/2000	Christine Icard-Liepkalns		2918

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ROSS J. OEHLER
AVENTIS PHARMACEUTICALS INC.
ROUTE 202-206
MAIL CODE: D303A
BRIDGEWATER, NJ 08807

EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/595,947	ICARD-LIEPKALNS ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 26 July 2004.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-66 is/are pending in the application.

4a) Of the above claim(s) 11-18,31-38 and 47-66 is/are withdrawn from consideration.

5)☒ Claim(s) 6,21,22,24,26-30,40 and 42-46 is/are allowed.

6)☒ Claim(s) 1,3-5,8,9,19,20,23,25,39 and 41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/331,358.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-66 are pending.

Applicants' amendment filed July 26, 2004 is acknowledged. Applicants' response has been fully considered. Claims 1, 3-6, 8 and 9 have been amended, and claims 2, 7 and 10 have been cancelled. Claims 11-18, 31-38 and 47-66 are non-elected inventions and remain withdrawn from consideration. Therefore, claims 1, 3-6, 8, 9, 19-30 and 39-46 are examined.

This application contains claims 11-18, 31-38 and 47-66 drawn to an invention nonelected with traverse in the response filed January 9, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claims 2 and 7 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' cancellation of the claim in the amendment filed July 26, 2004.

3. The previous rejection of claims 1-8, 19-26 and 39-42 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claim in the amendment, and applicants' response at pages 16-18 in the amendment filed July 26, 2004.

Claim Rejections - 35 USC § 102

4. The previous rejection of claims 1-6, 19, 21 and 23-26 under 35 U.S.C. 102(b) as anticipated by Bejanin *et al.* (J. Neurochemistry 58, 1580-1583, 1992), is withdrawn in view of

applicants' amendment to the claim, applicants' cancellation of the claim, and applicants' response at page 18 in the amendment filed July 26, 2004.

5. The previous rejection of claims 1-7, 9, 19, 21 and 23-26 under 35 U.S.C. 102(e) as anticipated by Anderson *et al.* (U. S. Patent 6,566,496), is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claim, and applicants' response at pages 18-20 in the amendment filed July 26, 2004.

Informalities

The disclosure is objected to because of the following informalities:

6. The specification recites amino acid and nucleotide sequences in Fig. 3, however, the sequence identifier "SEQ ID NO:" is not indicated in the Description of the Drawings (pages 10-11). Applicant must comply with the requirements of sequence rules (37 CFR 1.821-1.825) to include all the sequences in the sequence listing and to identify each sequence with a "SEQ ID NO:". Appropriate correction is required.

In response, applicants have amended the Description of the Drawings for Figs. 1, 2 and 4 to include the "SEQ ID NO:", however, the "SEQ ID NO:" is not indicated in the Description of the Drawings for Fig. 3.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 3-5, 8, 19, 20, 23, 25, 39 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3-5, 8, 19, 20, 23, 25, 39 and 41 are directed to a nucleic acid comprising at least 100 consecutive nucleotides of SEQ ID NO:1, or a complementary polynucleotide sequence thereof, optionally with a marker compound (claims 1 and 8); a nucleic acid comprising at least 80%, or 85%, 90%, 95% or 98% sequence identity to the nucleic acid comprising SEQ ID NO:1, or a complementary polynucleotide sequence thereof (claims 3, 4); a nucleic acid that hybridizes under high stringency conditions with a nucleic acid comprising SEQ ID NO:1, or a complementary polynucleotide sequence thereof (claim 5); and a recombinant vector (claims 19 and 20), a recombinant host cell (claims 23 and 25) and a pharmaceutical composition comprising the nucleic acid (claims 39 and 41). Wile the specification indicates that the invention relates to a nucleic acid having at least 80%, 85%, 90%, 95% or 98% sequence identity to a nucleic acid comprising SEQ ID NO:1; to a nucleic acid comprising at least 10, 12, ...100, 200 or 500 consecutive nucleotides of SEQ ID NO:1; and to nucleic acid hybridizing under high stringency conditions with a nucleic acid comprising SEQ ID NO:1 (page 30, lines 1-5; page 66, lines 5-25; page 30, line 21-page 31, line 4), the specification does not disclose a genus of variants for a nucleic acid comprising at least 100 consecutive nucleotides of SEQ ID NO:1, a nucleic acid comprising at least 80% sequence identity to the nucleic acid comprising SEQ ID NO:1; or a nucleic acid that hybridizes under high stringency conditions with a nucleic acid comprising SEQ ID NO:1.

The specification discloses nucleic acids encoding basic helix-loop-helix (bHLH) polypeptides, Relax and hngn3, and the nucleic acid comprises a polynulceotide sequence of (a) SEQ ID NO:1 or of a complementary polynucleotide sequence thereof; or (b) SEQ ID NO:9 or of a complementary polynucleotide sequence thereof (page 29, lines 22-26); comparison of amino acid sequences of the bHLH domain of Relax with other proteins of the bHLH family indicates the bHLH domain of Relax shares 68% identity with the bHLH unit of the protein NeuroD, however, Relax exhibits total absence of sequence identity, outside the bHLH domain, with other members of the family (Example 3, Fig. 2); and a new cDNA encoding the human neurogenin3 (hngn3; SEQ ID NO:10) peptide is identified and the nucleic acid is 1330 base pair long (SEQ ID NO:9; Example 7). However, the specification does not describe a genus of variants for a fragment or variant of SEQ ID NO:1 or a nucleic acid that hybridizes under high stringency conditions with a nucleic acid comprising SEQ ID NO:1. A single species of the nucleotide sequence of SEQ ID NO:1 does not provide original descriptive support for a genus of variants for fragments or variants of SEQ ID NO:1 or a nucleic acid that hybridizes under high stringency conditions with a nucleic acid comprising SEQ ID NO:1. The variants for a fragment or variant of SEQ ID NO:1 or a nucleic acid that hybridizes under high stringency conditions with a nucleic acid comprising SEQ ID NO:1 do not meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does

not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Applicants have described nucleic acids (e.g., SEQ ID NO:1 or 9) encoding basic helix-loop-helix (bHLH) polypeptides, Relax and hngn3, however, a genus of variants for fragments or variants of SEQ ID NO:1 or a nucleic acid that hybridizes under high stringency conditions with a nucleic acid comprising SEQ ID NO:1 have not been described nor disclosed.

The skilled artisan cannot envision all the contemplated nucleotide sequences for variants of fragments or variants of SEQ ID NO:1 or a nucleic acid that hybridizes under high stringency conditions with a nucleic acid comprising SEQ ID NO:1. The detailed sequences of variants or fragments of SEQ ID NO:1 must be taught, therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of preparation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF'S were found unpatentable due to lack of written description for the broad class.

The claims are drawn to a nucleic acid of a fragment or variant of SEQ ID NO:1 or a nucleic acid that hybridizes under high stringency conditions with a nucleic acid comprising SEQ ID NO:1, or a recombinant vector, recombinant host cell or a pharmaceutical composition comprising the nucleic acid, however, the specification does not provide original descriptive

support over the instantly claimed genus of variants for the nucleotide sequences of fragments or variants of SEQ ID NO:1.

Therefore, only those embodiments described and disclosed meet the written description requirement and not the full breadth of the claim meets the written description provision of 35 USC 1 12, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

In response, applicants indicate that the Examiner has misinterpreted the limitations of claims 3 to 6, which are directed to nucleic acids that are characterized by their level of identity (e.g., at least 80% identity) to SEQ ID NO: 1, and there are no functional limitations in these claims; considering the wide availability of programs that can align nucleotide sequences and determine percent identity, it would be routine for the skilled artisan to identify nucleic acids that are 80% identical to SEQ ID NO: 1; claim 5 is directed to nucleic acids that hybridize under high stringency conditions to SEQ ID NO: 1, hybridization and high stringency conditions are discussed in the specification (page 15, line 22, to page 18, line 3), the skilled artisan would recognize that hybridization techniques have been available for decades and that applicants would be able to utilize such techniques to identify hybridizable nucleic acids and sequencing of the nucleic acid is routine (pages 15 and 16 of the response).

The response has been considered, however, the argument is not found persuasive because the specification only identify a nucleotide sequence of SEQ ID NO:1, it does not

describe numerous variants for nucleotides which have at least at least 100 consecutive nucleotides of SEQ ID NO:1 (1460 nucleotides), at least 80% sequence identity to SEQ ID NO:1, or a nucleic acid that hybridizes under high stringency conditions with a nucleic acid comprising SEQ ID NO:1. Although the program to align the nucleotide sequences and the hybridization technique are known, the description of the representative species for fragments or variants of SEQ ID NO:1 is not provided in the specification, thus, the skilled artisan cannot envision all the contemplated nucleotide sequences. Since applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "said isolated nucleic acid" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

9. Claims 1, 3-5, 8, 9, 19, 20, 23, 25, 39 and 41 are rejected. It appears claims 6, 21, 22, 24, 26-30, 40 and 42-46 are allowable over art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. CMK
Patent Examiner

CMK
October 8, 2004

JON WEBER
SUPERVISORY PATENT EXAMINER